



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,894	04/27/2001	Lu-Kwang Ju	UA-338	5277
7590	01/30/2004		EXAMINER	
George W Moxon II, Esquire Roetzel & Andress 222 South Main Street Akron, OH 44308			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/830,894	JU, LU-KWANG
	Examiner	Art Unit
	Irene Marx	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 and 6-70 is/are pending in the application.
 - 4a) Of the above claim(s) 35-70 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6-34 and 71 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/30/03 has been entered.

Claims 1-4, 6-34 and 71 are being considered on the merits. Claims 35-70 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-4, 6-34 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The “selection” process used is not clearly delineated in claim 1. In addition, It is uncertain how “an alternative oxidant” is identified for any and all microorganisms, the nature of which is not determined.

Inasmuch as the claims as written are directed to a process using mixed cultures of microorganisms, one of ordinary skill in the art cannot determine the process conditions with any specificity or particularity.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's argument that a microorganism is selected based on the knowledge that it is capable of producing a desired biological product is noted. However, the claim designated invention requires the selection to be based on utilization of oxygen or an alternative oxidant source. With regard to the “desire” to form a product, it is unclear how one of ordinary skill in the art is to determine what is desired. The information in the as-filed specification is not specific or particular regarding methodology to be used in the selection process and is limited to the use of *Pseudomonas aeruginosa* and the production of rhamnolipids as the “desired” product. The broad laundry lists of microorganisms as well as the broad laundry lists of products lack specific protocol to screen for the capability of production of a particular desired product.

The rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 10, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by *Varma et al.*

The claims are directed to the production of a biological product with microorganisms including bacteria, yeasts, molds and archaea in the presence of an alternative oxidant source under aerobic conditions such that the strain may utilize the alternative oxidant source.

Varma et al. disclose the production of cells of the microorganism *E. coli* in the presence of the alternative oxidant source acetate or fumarate under aerobic conditions such that the strain uses the alternative oxidant source. See, e.g., page 3730, col. 2, paragraph 4 et seq.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the oxidant is now supplied in the culture. In the reference process, it is noted that acetate and fumarate are provided indirectly by supplying glucose to the culture medium.

With respect to the alleged definition of “alternative oxidants”, it is requested that the location of this definition in the specification be indicated. It was not found. The PTO must give claim words their broadest reasonable meaning in their ordinary usage, as understood by one of ordinary skill in the art taking into account whatever enlightenment by way of definitions or otherwise that may be afforded written description contained in the applicant's specification. *In re Morris*, 127 F.3d 1048, 44 U.S.P.Q.2d (Fed. Cir. 1997).

Regarding the contentions regarding the lack of a “desired product” in Varma, it is noted that the interpretation of “desired” is unrestricted, and, in fact, includes any product whatsoever. With respect to claim 2, Applicants' attention is directed to Figure 11, wherein the concentration of various recovered products is shown, such as cells, acetate, formate and ethanol. All of these products constitute “desired quantity of a biological product”. Moreover, the cells include products such as proteins, lipids, carbohydrates, enzymes, etc. etc.. With regard to pH and temperature, there is no indication that a desired pH and temperature are not maintained in Varma as alleged. No specific level and no particular time-frame are claim designated.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-4, 6, 10, 13, 15, 17-20, 22, 27-29, 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Giani *et al.*.

The claims are directed to the production of a biological product with a microorganism including bacteria, yeasts, molds and archaea in the presence of an alternative oxidant source under aerobic conditions such that the strain may utilize the alternative oxidant source.

Giani *et al.* disclose the production of cells of the microorganism *Pseudomonas aeruginosa* in the presence of the alternative oxidant source NaNO₃ under aerobic conditions such that at least a portion of the cells uses the alternative oxidant source when the maximum oxygen supply is less than the cells' oxygen requirements.. See, e.g., col. 5, lines 25-67 and Example 1.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The basis for Applicants' allegation that the reference does not teach maintaining the culture medium at a desired pH is unclear, inasmuch as no specific level and no particular time-frame are claim designated. The fact that the pH is ignored in Giani *et al.* cannot be interpreted to mean that it is not maintained at “a desired pH”. That the specification wishes the pH of the

culture to be maintained in an optimal range is immaterial to the claims being examined. Moreover, it is apparent that Giani *et al.* maintain “an optimal range” for their purposes.

With respect to the functional limitations in claim 1, applicant has not shown with objective evidence that in Giani *et al.* the supply of the alternative oxidant is insufficient to cause at least one microorganism (a portion) within the culture medium to utilize the alternative source for cellular respiration when the oxygen requirements for cellular respiration is greater than the maximum rate of oxygen supply to the culture medium. It is noted that the aeration level is substantially decreased after the 30th hour (Col. 9, lines 38-43). The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-4, 6-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giani *et al.* taken with Brock and Wagner *et al.* for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to the production of a biological product with microorganisms including bacteria, yeasts, molds and archaea in the presence of an alternative oxidant source under aerobic conditions such that the strain may utilize the alternative oxidant source.

Response to Arguments

Applicant’s arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that Giani *et al.* teaches away from the claimed invention because pH is not controlled in the course of fermentation. However, maintenance at a “desired pH” cannot be equated with pH control. Moreover, it is apparent that Giani *et al.* maintains the culture medium at a desired pH, which is suitable for the production of the desired product.

Applicant also argues that in Giani *et al.* the aeration rate can be adjusted. However, this does not necessarily mean that at no time will the oxygen requirements for cellular respiration of the microorganisms within the culture medium be greater than the maximum rate of oxygen supply to the culture medium, such that at least one microorganism within the culture medium will utilize the alternative oxidant source for cellular respiration, especially after the oxygen supply rate is decreased.

With respect to applicant’s criticism that the combination of references would change the principle of operation of the prior art, it is noted that even though the process of Giani *et al.* may not disclose all of the metabolic processes, principles of operation and ramifications of supplying an alternative oxidant to the culture, the claimed process is substantially taught by the reference.

Brock is cited to demonstrate that many alternative oxidants are known in the art, such as fumarate, sulfate, sulfur, ferric ion and nitrite (See, e.g., pages 113-114). Wagner is cited to demonstrate that various substrates including small acids, such as malonate, succinate, pyruvate or malate, or fatty acids such as stearic acid are routinely used in this art in media for microorganisms, including *Pseudomonas*. (See, e.g., col. 3). In addition, Wagner *et al.* was cited to demonstrate the routine use of nutrient limitation in the cultivation of bacteria, specifically by limiting magnesium or nitrogen for the production of rhamnolipids with *Pseudomonas* (See, e.g., Examples 2-3).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 19880; *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have been motivated to modify the process of cultivation of Giani *et al.* wherein an alternative oxidant is supplied, by the substitution of nitrate by other oxidants, as suggested by Brock as well as the use of expedients such as nutrient limitation and various carbon substrates, as suggested by the teachings of Wagner *et al.* for the expected benefit of maximizing the production of useful biological products produced by microorganisms suitable for the pharmaceutical industries and for foods or feed, for example.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0926.

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651